CLAIMS

We claim:

1. A system for detecting the effectiveness of a sterilization treatment, comprising a biological indicator, a solid support, a liquid medium, and a multiangle light scattering instrument.

2. The system of claim 1, wherein the biological indicator is a spore selected from the group consisting of a *B. subtilis* spore, and a *B. stearothermophilus* spore.

3. The system of claim 2, wherein the biological indicator is a *B. subtilis* spore.

4. The system of claim 1, wherein the solid support is selected from the group consisting of an adsorbent filter, a membrane, a matrix, glass, plastic, and metal.

5. The system of claim 4, wherein the support is glass in the form of a glass slide or a glass vial.

6. The system of claim 1, wherein the multiangle light scattering instrument is selected from the group consisting of a DAWN Model B MALS photometer, and a DAWN Model F MALS photometer.

7. The system of claim 1, wherein the sterilization treatment is selected from the group consisting of a chemical sterilization treatment, and a physical sterilization treatment.

8. The system of claim 7, wherein the chemical sterilization treatment is selected from the group consisting of an ethylene oxide sterilization treatment, a hydrogen peroxide sterilization treatment, a tetrasilver tetraoxide sterilization treatment, and an ozone sterilization treatment.

9. The system of claim 7, wherein the physical sterilization treatment is selected from the group consisting of a radiation sterilization treatment, a gas plasma sterilization treatment, a steam sterilization treatment, and a dry heat sterilization treatment.

10. The system of claim 1, wherein the liquid medium is selected from the group consisting of water, a brain heart infusion broth medium, a nutrient broth, and a trypticase soy broth.

11. A method of assessing the viability of a spore after a sterilization treatment, comprising:

(a) exposing a spore to a sterilization treatment;

(b) examining the treated spore using multiangle light scattering; and

(c) evaluating a difference between the multiangle light scattering of the treated spore and a multiangle light scattering of a like spore not exposed to a sterilization treatment to determine whether the treated spore is viable.

12. The method of claim 11, wherein the spore and the like spore are selected from the group consisting of a *B. subtilis* spore, and a *B. stearothermophilus* spore.

13. The spore of claim 12, wherein the spore and the like spore are *B. subtilis*.

14. The spore of claim 12, wherein the spore and the like spore are *B. stearothermophilus*.

15. The method of claim 11, wherein the sterilization treatment is selected from the group consisting of a chemical sterilization treatment, and a physical sterilization treatment.

16. The method of claim 15, wherein the chemical sterilization treatment is selected from the group consisting of an ethylene oxide sterilization treatment, a hydrogen peroxide sterilization treatment, a tetrasilver tetraoxide sterilization treatment, and an ozone sterilization treatment.

17. The method of claim 15, wherein the physical sterilization treatment is selected from the group consisting of a radiation sterilization treatment, a gas plasma sterilization treatment, a steam sterilization treatment, and a dry heat sterilization treatment.

18. The method of claim 11, further comprising examining the like spore using multiangle light scattering prior to the sterilization treatment of the spore in step (a) to provide a standard multiangle light scattering data set for use as the multiangle light scattering of the like spore in step (c).

19. The method of claim 18, further comprising storing the standard multiangle light scattering data to assess viability of a second like spore after sterilizing the second like spore using the sterilization treatment of step (a).

20. The method of claim 11, further comprising incubating the treated spore with a growth medium prior to step (b).

21. The method of claim 20, wherein the growth medium is selected from the group consisting of trypticase soy broth, nutrient broth, and brain heart infusion broth.

22. The method of claim 20, further comprising incubating the spore up to about 24 hours prior to step (b).

23. The method of claim 20, further comprising heat-shocking the treated spore prior to incubating the treated spore with the growth medium.

24. The method of claim 11, wherein the sterilization treatment is selected from the group consisting of a steam sterilization treatment, and an ozone sterilization treatment, and the method further comprises examining the treated spore directly after the sterilization treatment.

25. A method of assessing the efficacy of a sterilization treatment, comprising

(a) exposing a biological indicator to a sterilization treatment;

(b) examining a like biological indicator using multiangle light scattering to create a standard profile;

(c) examining the treated biological indicator using multiangle light scattering to create a post-sterilization profile; and

(d) comparing the post-sterilization profile of the treated biological indicator to the standard profile of the like biological indicator, wherein a difference between the post-sterilization profile of the treated biological indicator and the standard profile of the like biological indicator indicates the efficacy of the sterilization treatment.

26. The method of claim 25, wherein the biological indicator and the like biological indicator are *B. subtilis* spores.

27. The method of claim 25, further comprising using a photometer selected from the group consisting of a DAWN Model B MALS photometer, and a DAWN Model F MALS photometer for multiangle light scattering.

28. The method of claim 25, wherein the sterilization treatment is selected from the group consisting of a physical sterilization treatment, and a chemical sterilization treatment.

29. The method of claim 28, wherein the chemical sterilization treatment is selected from the group consisting of a tetrasilver tetraoxide sterilization treatment, an ethylene oxide sterilization treatment, a hydrogen peroxide sterilization treatment, and an ozone sterilization treatment.

30. The method of claim 28, wherein the physical sterilization treatment is selected from the group consisting of a radiation sterilization treatment, a gas plasma sterilization treatment, a dry heat sterilization treatment, and a steam sterilization treatment.

31. The method of claim 25, wherein the sterilization treatment is selected from the group consisting of a steam sterilization treatment, and an ozone sterilization treatment, and the method further comprises examining the treated spore directly after the sterilization treatment.

32. A method of detecting a change in a biological indicator exposed to a sterilization treatment, comprising exposing a biological indicator to a sterilization treatment, and comparing a multiangle light scattering of the treated biological indicator to a multiangle light scattering of a like biological indicator not exposed to a sterilization treatment, wherein a difference between the multiangle light scattering of the treated biological indicator and the multiangle light scattering of the like biological indicator indicates a change in the treated biological indicator.

33. The method of claim 32, further comprising incubating the treated biological indicator with a growth medium for up to about 24 hours before examining the multiangle light scattering of the biological indicator.

34. The method of claim 33, further comprising heat-shocking the biological indicator prior to incubating the biological indicator with the growth medium.

35. The method of claim 32, further comprising using an instrument selected from the group consisting of a nephelometer, and a photometer to examine the multiangle light scattering of the biological indicator.

36. The method of claim 32, wherein the sterilization treatment is selected from the group consisting of a steam sterilization treatment, and an ozone sterilization treatment, and the method further comprises examining the treated spore directly after the sterilization treatment.

37. A kit for assessing the viability of a spore after a sterilization treatment, the kit comprising about 2×10^8 spores adsorbed onto a solid support, a multiangle light scattering photometer, and a liquid medium.

38. The kit of claim 37, further comprising an instructional material for the use of the kit.